REMARKS

The Final Office Action mailed February 3, 2009, has been carefully reviewed. Upon entry of the amendments presented above, the claims in the application will be claims 29-45. These claims are patentable for the same reasons as already set forth in previous replies to previous office actions, respectfully repeated by reference, and for the additional reasons set forth below. Applicant respectfully requests favorable reconsideration and allowance.

Claims 1, 3, 4, 16 and 19 were finally rejected under § 102 as anticipated by Heiligenstein. The rejection is again respectfully traversed for the reasons of record, respectfully repeated by reference, and for the additional reasons set forth below.

First, Applicant takes strong issue with the examiner's repetition of this rejection after applicants have pointed out that there is no example in Heiligenstein of the claimed subject matter. The Examiner has brushed this argument aside, stating as follows:

> The Examiner finds this argument unpersuasive, because the reference disclosed venlafaxine can also be used (see pg. 3, line 8; pg. 14, line 48), wherein venlafaxine and duloxetine are classified in the same drug category of

norepinephrine uptake inhibitor.

The Examiner has misapplied § 102 which requires that the reference "must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements 'arranged as in the claim.'" *Connell v. Sears…*, 220 USPQ 193 (Fed. Cir. 1983)", as quoted in *Net MoneyIn v. VeriSign*, 88 USPQ2d 1751, 1758 (Fed Cir 2008). Venlafaxine is not disclosed in Heiligenstein "arranged as in the [Applicant's] claim."

Heiligenstein does not anticipate any of claims 1, 3, 4, 16 and 19, i.e. what these claims recite is novel. As to the issue of whether or not it would have been obvious under § 103 for the person of ordinary skill in the art (1) to have substituted venlafaxine hydrochloride for the duloxetine, and (2) somehow have come up with applicant's claimed subject matter is an issue addressed previously, as well as further below, but is not an issue under § 102.

Claims 1, 3, 4, 16 and 19 have now been deleted without prejudice to Applicant's rights to pursue these and/or similar claims at a later date, such as in a continuing application, if Applicant chooses to do so, Applicant in such a case relying on §§ 120 and 119, without any penalty whatsoever.

Heiligenstein not only does not disclose, but also does not teach a composition comprising 30-60% w/w drug and 2-15%

w/w hydrophobic polymer as in claim 31, or a method for preparing such a composition.

Thus, new claim 31 is clearly not anticipated by Heiligenstein. Therefore, claim 31 and all of the claims dependent thereon should be allowable over Heiligenstein.

Withdrawal of any rejection under § 102 based on Heiligenstein is in order and is respectfully requested.

Claims 1-7, 9, 10, 12-22, 23 and 25-30 have been finally rejected under § 103 as obvious from Heiligenstein. This rejection is again respectfully traversed for the reason of record, respectfully repeated by reference, and for the additional reasons set forth below.

The Examiner maintains that the general disclosure of Heiligenstein with the duloxetine example teaches one of ordinary skill in the art to simply use venlafaxine in place of duloxetine to arrive at the Applicant's invention. The Examiner bases this conclusion on the fact that "*...venlafaxine and duloxetine are classified in the same drug category of nonepinephrine uptake inhibitors.*" Applicant respectfully traverses this rejection and argument, primarily for the reason that the pharmacological and/or clinical effects of the active pharmaceutical ingredient of the present invention (i.e. venlafaxine) and its similarity to the biological effects produced by duloxetine are of no relevance to the instantly claimed composition, a key aim of which is to

enable controlled release of the highly soluble venlafaxine, and this would be well understood by those skilled in the art. It should be emphasized in this regard that many pharmaceutically-active compounds assigned to the same class on the basis of their common biological activities (i.e. the effect of the drug on the patient's body) may differ considerably with respect to their pharmacokinetic properties (i.e. the effect of the patient's body on the drug).

Thus, as discussed in Applicant's response dated April 5, 2007, venlafaxine is highly soluble in water as compared with most other anti-anxiety/SSRI compounds, namely, the compounds disclosed in Heiligenstein and especially duloxetine (the only demonstrated drug in Heiligenstein). In fact, duloxetine (0.00296 mg/ml; source: http://www.drugbank.ca/drugs/DB00476) is nearly two hundred thousand-fold (!) less water soluble than venlafaxine (572 mg/ml; para. [0004] of instant application). Thus the stability problems (detailed in Applicant's former response) which are addressed and solved in Applicant's claims are not, indeed cannot be, addressed, disclosed or even hinted at in Heiligenstein.

Heiligenstein teaches only at best how to handle a slightly water soluble drug such as duloxine, but provides no teaching on how to prepare an extended release composition comprising a highly soluble drug such as venlafaxine. Specifically, Heiligenstein does not teach or suggest a

composition comprising 30-60% w/w venlafaxine and 2-15% w/w hydrophobic polymer as in claim 31 or a method for preparing such a composition. Heiligenstein does not enable the person of ordinary skill in the art to reach Applicant's claimed composition because Heiligenstein only teaches one how to achieve the Heiligenstein composition with a slightly water soluble drug, but does not teach the person of ordinary skill in the art how to achieve such a composition with a highly water soluble drug.

The Examiner's argument that amounts of specific ingredients in a composition is a parameter that a person of ordinary skill in the art could routinely optimize with expected success, is not relevant in this case due to the different physical properties of Heiligenstein's demonstrated drug and the instantly claimed drug.

Heiligenstein teaches using 8% w/w drug and 25.8% w/w hydrophobic polymer. Heiligenstein gives no direction as to the modifications needed to these amounts when using a highly water soluble drug. In this case these modifications are not known or obvious to one skilled in the art. Rather reaching the ranges claimed in new claim 31 required extensive experimentation (as described in Applicant's specification).

Moreover, if Heiligenstein teaches a composition comprising venlafaxine, as maintained by the Examiner, then Heiligenstein teaches only a composition comprising 8% w/w venlafaxine and 25.8% w/w hydrophobic polymer layer. One skilled

in the art using 8% w/w venlafaxine and 25.8% w/w hydrophobic polymer layer as taught by Heiligenstein would not obtain a successful result. No direction is given in Heiligenstein as to how to modify these amounts in order to obtain a successful result.

Thus, new claim 31 is not obvious from Heiligenstein, nor are claims 29 and 30. Therefore, these claims and all the claims dependent thereon define non-obvious subject matter over Heiligenstein.

Withdrawal of the rejection is in order and is respectfully requested.

Respectfully submitted,

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